

REMARKS

The claims have been amended to better define the invention. The upper limit of the hydrogen peroxide concentration in independent claims 1, 9, 20, 22, 24, 26, 28, 30, and 32 has been reduced from 20 w/w % to 8 w/w%. The subject matter removed from these claims has been added to new dependent claims 46 to 54 which cover concentrated versions of the present inventive solution having a hydrogen peroxide concentration of up to 20 w/w%. As a result of these changes, claims 3 and 11 have been cancelled for being of marginal utility. Numerical values formerly represented as "X.0" are now represented simply as "X". The ".0" implies a level of accuracy not intended by the Applicant. Applicant submits that no new matter has been added by way of these amendments.

The objections raised in the Examiner's Report will now be discussed.

Double Patenting

To overcome the non-statutory double patenting rejection, Applicant hereby submits a terminal disclaimer in compliance with 37 CFR 1.321(c). Thus, the term of any patent to be granted for this application will not extend beyond the term of Applicant's issued US patent 6,346,279.

Obviousness

Examiner has rejected original claims 1 to 45 under 35 U.S.C. 103(a) for being obvious in view of WO 98/11777 to Scoville et al., US 4,637,899 to Kennedy, Jr., and Block, "Disinfection, Sterilization, and Preservation" (Lea & Febiger, 4th ed., 1991, Philadelphia). Applicant acknowledges that the present ground of rejection is applicable only to the extent that the claims read on subject matter that is not encompassed by the claimed subject matter of Applicant's US patent no. 6,346,279. In this regard, Applicant notes that the subject matter covered by amended claim 1 and which is not already covered by the claims of this issued patent is as follows:

1. a pH range of 3 to 7;
2. a hydrogen peroxide concentration of from 0.01 to 0.05 w/w %;

3. all species and combinations of species of phosphorus based acids other than phosphoric acid alone and phosphoric acid in combination with 1-hydroxyethylidene-1,1-diphosphonic acid;
4. all species and combinations of species of anionic surfactants originally claimed other than the C8 to C16 alkyl aryl sulfonic acids and alkali metal and ammonium salts thereof.

Applicant has elected, without traverse, 1-hydroxyethylidene-1,1-diphosphonic acid, as the single disclosed species of the phosphorus-based acid, and C8-C16 alkyl aryl sulfonic acids and alkali metal and ammonium salts thereof, as the single disclosed species of anionic surfactant. Nonetheless, in view of the new evidence being filed concurrently herewith and consisting of the affidavit of Jose Ramirez sworn on March 31, 2003, Applicant requests that the Examiner allow all originally disclosed anionic surfactant and phosphorus-based acid species to save the Applicant the time and expense of pursuing such species in additional future patent applications.

There are presently 9 independent claims, namely claims 1, 9, 20, 22, 24, 26, 28, 30 and 32. All claims, both dependent and independent, include the limitations contained in claim 1 and should be found allowable if claim 1 is allowable. Claim 1 is reproduced below:

1. (currently amended) An aqueous disinfecting or sanitizing solution having a pH of from 1 to 7 and *consisting essentially of*:
 - i) hydrogen peroxide in a concentration of from 0.01 to 8 wt./wt.% of the solution;
 - ii) at least one phosphorus-based acid in a concentration range of from 0.05 to 8 wt./wt.% of the solution;
 - iii) at least one anionic surfactant selected from the group consisting of C8 to C16 alkyl aryl sulfonic acids and alkali metal and ammonium salts thereof, sulfonated C12 to C22 carboxylic acids and alkali metal and ammonium salts thereof, C8 to C22 alkyl diphenyl oxide sulfonic acids and alkali metal and ammonium salts thereof, naphthalene sulfonic acids and alkali metal and ammonium salts thereof, C8 to C22 alkyl sulfonic acids and alkali metal and ammonium salts thereof,

- alkali metal C8 to C18 alkyl sulfates, and mixtures thereof, in a concentration range of from 0.02 to 5 wt./wt.% of the solution; and
- iv) the remainder to 100 wt./wt.% water.

While extensive literature exists on the germicidal properties of hydrogen peroxide, acids and anionic surfactants, the main problem with prior art hydrogen peroxide formulations is that not enough germicidal activity is shown under realistic contact times and practical or economically feasible concentrations. The present invention provides a formulation which is effective even at very low concentrations of hydrogen peroxide as will be discussed further below. The inventive formulation exhibits enhanced germicidal activity due the synergistic interaction of the individual components thereof. The particular selection of the components of the present invention formulation and the enhanced level of activity resulting from the selection are not taught by the cited references. Based on published data, including information disclosed by the cited references, this enhanced level of activity is unexpected.

The Examiner cited Scoville et al. as the primary reference and Block and Kennedy, Jr. as secondary references. Scoville et al. teaches a hydrogen peroxide disinfectant solution which is stable over long periods of time and has anti-corrosive properties (page 3, lines 5-9). It is not concerned with providing a hydrogen peroxide disinfectant formulation with enhanced activity. The formulation contains hydrogen peroxide in an amount of from about 0.5 to about 50 w/w %, an organic or inorganic acid in a concentration of from about 0.001 to about 10 w/w %, and a corrosion inhibitor comprising from about 0.1 to about 30 w/w % of 1,2,3-benzotrizole and alkylene glycol.

Scoville et al. does not teach that using the selected anionic surfactants of the present invention will result in an unexpected boost in the disinfection ability of the base composition. In fact, this reference teaches the use of surfactants as being optional (see page 7, lines 23-30). If used, the surfactants must be compatible with hydrogen peroxide in acidic aqueous media, that is, it must be relatively stable against oxidation and decomposition in the presence of acidic aqueous hydrogen peroxide. Although long lists of surfactants are recited which include some of the anionic surfactants presently claimed, it would not be obvious to select the presently claimed anionic surfactant from these lists absent some teaching or suggestion to do so.

Note that the example formulations described at page 12 rely on hydrogen peroxide in combination with peracetic acid. These formulations were tested on *Bacillus subtilis* var. *niger* spores. Peracetic acid is a well known spore killer and the efficacy data presented in tables 1 to 3 are not surprising. See the enclosed article by Baldry, M.G.C., "The bacterial, fungicidal and sporicidal properties of hydrogen peroxide and peracetic acid" (1983), Journal of Applied Bacteriology, 34, 417-423, and especially page 418 and 421 thereof.

Block has been cited to establish that hydrogen peroxide, acids and surface active agents are known to possess individual disinfecting properties (pp. 167-180, 256-271). However, based on the published data relating to the germicidal properties of individual components, one would not expect the rate of activity demonstrated by solutions according to the present invention.

Kennedy, Jr. was cited to show that solubilizing alcohols such as isopropanol and a surfactant such as an alkyl sulfonated diphenyl oxide are known corrosion inhibitors. This reference is therefore not pertinent to the patentability of claim 1 and will not be discussed for the purpose of this response.

SYNERGY OF INVENTION

The Ramirez affidavit provides evidence of efficacy and unexpected synergy of the presently claimed solution. This evidence is commensurate in scope with the scope of claim 1. The examples contained in the affidavit will now be summarized. Examiner is invited to consult the affidavit for further details.

Example A demonstrates the synergy between the individual ingredients of the present solution which would not be expected based on the teachings of the cited references. Applicant submits that the information contained in Example A is sufficient to rebut the *prima facie* presumption of obviousness. The results for formulations A2 and A3 indicate that the hydrogen peroxide alone and the anionic surfactant alone are not as effective as the combination of the two ingredients. The activity of solutions containing the combination is not predictable based on the efficacy results for the individual components. Examples B to E have been provided to support the patentability of the subject matter which does not overlap with the claims of Applicant's issued US patent.

Example B shows that an effective bactericide can be achieved by a solution (as claimed) in which the phosphorus-based acid is any one of 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP), amino tri(methylene phosphonic acid (ATMP), and tripolyphosphoric acid. Example E demonstrates that the HEDP as the sole phosphorus-based acid, when combined with the C6 Dowfax hydrotrope, provides a solution which is also an effective virucide.

Example C demonstrates the efficacy of solutions according to the present invention which differ in terms of the species of anionic surfactant used. This example demonstrates that numbers of all originally disclosed species of anionic surfactants are effective in providing a solution which is an effective bactericide.

Example D demonstrates that solutions according to the invention having pH values of 3.8, 5.0 and 6.0 are also effective bactericides.

In view of the Ramirez affidavit, Applicant submits that amended claim 1 should be found allowable, at least insofar as it reads on the elected species. As the other claims incorporate the limitations of independent claim 1, they should likewise be found allowable.

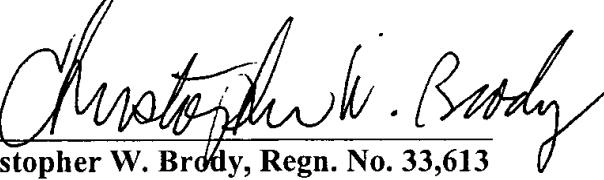
At this time, and despite Applicant's election, Applicant respectfully requests that the Examiner reconsider his position on the restriction requirement and allow the entire scope of claim 1 in light of the new evidence being filed with this response. This evidence establishes the synergy between or among each of the originally disclosed phosphorus-based acid and anionic surfactant species and the rest of the claimed ingredients. Applicant respectfully asks the Examiner to allow claims to all disclosed acid and surfactant species in order to save the Applicant time and expense associated with the filing of further applications directed to the non-elected species.

The Examiner is requested to telephone the undersigned if any further information is needed to resolve the issues raised in the Office Action.

As a result of the claim amendments, there are now 7 extra claims. Please charge Deposit Account Number 50-1088 in the sum of \$126 (7 x \$18/claim) for these extra claims (in excess of 20 total claims). Please also charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account Number 50-1088, and credit any excess payments to such account.

Again, reconsideration and allowance of this application are respectfully solicited.

Respectfully Submitted,
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By: 
Christopher W. Brody, Regn. No. 33,613

Place: Washington
Date: March 31, 2003
Tel. No.: 202.835.1753

Enclosure(s)

- Affidavit of Jose Ramirez, sworn on March 31, 2003 ;
- Article by Baldry, M.G.C., "The bacterial, fungicidal and sporicidal properties of hydrogen peroxide and peracetic acid" (1983), Journal of Applied Bacteriology; and
- Terminal Disclaimer.